

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
STEVE REYNOLDS, Plaintiff, vs. AUXILIUM PHARMACEUTICALS, INC. Defendants.	COMPLAINT AND JURY DEMAND Civil Action No.:14-cv-09750

COMPLAINT

Plaintiff, Steve Reynolds (“Plaintiff”), residing in North Hills, Los Angeles County within the State of California, by and through his undersigned counsel, hereby sues Defendant Auxilium Pharmaceuticals, Inc. (“Defendant”) and alleges as follows:

INTRODUCTION

1. This case involves the prescription drug Testim, which is manufactured, sold, distributed and promoted by Defendants, as a testosterone replacement therapy.
2. Defendants misrepresented that Testim is a safe and effective treatment for hypogonadism or "low testosterone," when in fact the drug causes serious medical problems, including life threatening cardiac events, strokes, and thrombolytic events.

3. Defendants engaged in aggressive, print, television and direct mail advertising campaigns for Testim. Further, Defendant engaged in an aggressive unbranded “disease awareness” campaign to alert men that they might be suffering from low testosterone.

4. As a result, diagnoses of low testosterone have increased exponentially. This has directly related to Testim’s sales increasing well over \$209 million per year.

5. However, consumers of Testim were misled as to the drug’s safety and efficacy, and as a result have suffered injuries including life-threatening cardiac events, strokes, and thrombolytic events.

PARTIES

6. Plaintiff is a natural person and a citizen of the State of California and used the prescription Testim as prescribed and directed by his physician.

7. Defendant Auxilium Pharmaceuticals, Inc. (hereinafter “Auxilium” or “Defendant”) is a Delaware corporation which has its principal place of business at 640 Lee Road, Chesterbrook, Pennsylvania 19087. Auxilium has conducted business and derived substantial revenue throughout the United States.

8. At all times relevant to this Complaint, Defendant was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription testosterone drug sold under the name Testim, throughout the United States.

JURISDICTION AND VENUE

9. This Court has jurisdiction over Defendants and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants and because the amount in controversy between Plaintiff and Defendants exceeds \$75,000, exclusive

of interest and cost, and because, among other reasons, Defendants have significant contacts with this district by virtue of doing business within this judicial district.

10. Venue is proper within this district pursuant to 28 U.S.C. § 1391.

GENERAL ALLEGATIONS

11. This action is for damages brought on behalf of Plaintiff who was prescribed and supplied with, received and who has taken and applied the prescription drug Testim, as tested, studied, researched, evaluated, endorsed, designed, formulated, compounded, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, prescribed, sold or otherwise placed in the stream of interstate commerce by Defendants. This action seeks, among other relief, general and special damages and equitable relief in order to enable Plaintiff to treat and monitor the dangerous, severe and life-threatening side effects caused by this drug.

12. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's injuries and damages.

13. At all times herein mentioned, the Defendants were engaged in the business of, or were successors in interest to, entities engaged in the business of research, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug Testim for the use and application by Plaintiff.

14. At all times herein mentioned, Defendants were authorized to do business within the state of residence of Plaintiff.

15. At all times herein mentioned, the officers and directors of Defendants participated in, authorized, and directed the production and promotion of the aforementioned product when

they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff herein.

16. Plaintiff files this lawsuit within the applicable limitations period of first suspecting that said drugs caused the appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiff's injuries at an earlier time because the injuries were caused without perceptible trauma or harm, and when Plaintiff's injuries were discovered their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that Plaintiff had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public and to the medical profession that the drug Testim is safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

OVERVIEW

17. Hypogonadism is a specific condition of the sex glands, which in men may involve the diminished production or nonproduction of testosterone.

18. A study published in the Journal of the American Medical Association ("JAMA") in August 2013 entitled "Trends in Androgen Prescribing in the United States, 2001-2011" indicated that many men who get testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue, and one quarter

of men did not even have their testosterone levels tested before they received a testosterone prescription.

19. Defendants coordinated an aggressive advertising campaign designed to convince men that they suffered from low testosterone. Defendant orchestrated national disease awareness media blitzes that purported to educate male consumers about the signs of low testosterone. The marketing campaigns included promotional literature placed in healthcare providers' offices and distributed to potential testosterone users, and online media.

20. The advertising campaigns suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These "symptoms" include listlessness, increased body fat, and moodiness—all general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone.

21. Defendants also sought to convince primary care physicians that low testosterone levels are widely under-diagnosed, and that conditions associated with normal aging could be caused by low testosterone levels.

22. While running disease awareness campaigns, Defendant promotes their product, Testim, as an easy to use topical testosterone replacement therapies. Defendant contrasts their products' at-home topical application with less convenient prescription testosterone injections, which require frequent doctor visits.

23. Defendants convinced millions of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on Defendants' promises of safety and ease. Although prescription testosterone replacement therapy had been available for years,

millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

24. What consumers received, however, were not safe drugs, but a product which causes life-threatening problems, including strokes and heart attacks.

25. Sales of replacement therapies has more than doubled by 2006, and are expected to triple to \$5 billion by 2017, according to forecasts by Global Industry Analysts. Shannon Pettypiece, *Are Testosterone Drugs the Next Viagra?*, May 10, 2012, Bloomberg Businessweek, *available at*: <http://www.businessweek.com/articles/2012-05-10/are-testosterone-drugs-the-next-viagra>.

26. The Defendants' marketing program sought to create the image and belief by consumers and physicians that low testosterone affected a large number of men in the United States and that the use of Testim is safe for human use, even though Defendants knew these to be false, and even though Defendants had no reasonable grounds to believe them to be true.

27. There have been a number of studies concluding that testosterone therapy causes a sudden increase in hematocrit, hemoglobin and estradiol, and associating its use with increased the risk of blood clots, heart attacks, and strokes.

28. In 2010, a New England Journal of Medicine Study entitled "Adverse Events Associated with Testosterone Administration" was discontinued after an exceedingly high number of men in the testosterone group were suffered adverse events.

29. In November of 2013, a JAMA study was released entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels" which indicated that testosterone therapy raised the risk of death, heart attack and stroke by about 30%.

30. On January 29, 2014, a study was released in PLOS ONE entitled “Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men” which indicated that testosterone use doubled the risk of heart attack with men aged 65 and older, and tripled the risk of a heart attack in younger men with a history of previous heart attacks.

FACTUAL ALLEGATIONS COMMON TO ALL CAUSES OF ACTION

31. The Food and Drug Administration approved Testim on October 21, 2002 for the treatment of adult males who have low testosterone. After FDA approval, Testim was widely advertised and marketed by Defendants as a safe and effective testosterone replacement therapy.

32. Testim is a hydroalcoholic gel containing testosterone. Testim is applied to the shoulders and upper arms. Testim enters the body through transdermal absorption.

33. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

34. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

35. In men, testosterone levels normally begin a gradual decline after the age of thirty.

36. The average testosterone levels for most men range from 300 to 1,000 nanograms per deciliter of blood. However, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Resultantly, many men who fall into the hypogonadal range one day will have normal testosterone levels the next.

37. Testim may produce undesirable side effects to patients who use the drug, including but not limited to, cardiac events, myocardial infarction, stroke, and death.

38. In some patient populations, Testim use may increase the incidence of myocardial infarctions and death by over 500%.

39. In addition to the above, Testim has been linked to several severe and life changing medical disorders in both users and those who come into physical contact with users or the unwashed clothes of someone who applied Testim. Patients taking Testim may experience enlarged prostates and increased serum prostate-specific antigen levels.

40. Secondary exposure to testosterone can cause side effects in others. In 2009 the FDA issued a black box warning for testosterone prescriptions, advising patients of reported virilization in children who were secondarily exposed to the gel. Testosterone may also cause physical changes in women exposed to the drug and cause fetal damage with pregnant women who come into secondary contact with testosterone.

41. Defendants' marketing strategy, beginning in 2000, has been to aggressively market and sell their products by misleading potential users about the prevalence and symptoms of low testosterone and by failing to protect users from serious dangers that Defendants knew or should have known to result from use of its products.

42. Defendant successfully marketed testosterone by undertaking "disease awareness" marketing campaigns. These campaigns sought to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression, and lethargy were actually attributable to low testosterone.

43. Defendants' advertising program sought to create the image and belief by consumers and their physicians that the use of Testim was a safe method of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though Defendants knew or should have known these to be false, and even though the Defendants had no reasonable grounds to believe them to be true.

44. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using Testim. Defendants deceived potential Testim users by relaying positive information through the press, including testimonials from retired professional athletes, and manipulating hypogonadism statistics to suggest widespread disease prevalence, while downplaying known adverse and serious health effects.

45. In particular, in the warnings Defendants give in their commercials, online and print advertisements, Defendants fail to mention any potential cardiac or stroke side effects and falsely represents that Defendants adequately tested Testim for all likely side effects. Defendant concealed material relevant information from potential testosterone users and minimized user and prescriber concern regarding the safety of testosterone.

46. As a result of Defendants' advertising and marketing, and representations about its product, men in the United States pervasively seek out prescriptions for Testim. If Plaintiff in this action had known the risks and dangers associated with Testim, Plaintiff would not have taken Testim, and consequently would not have been subject to its serious side effects.

SPECIFIC FACTUAL ALLEGATIONS

47. Plaintiff was prescribed Testim and used it as directed prior to his injury.

48. Plaintiff is sixty-one (61) years of age, taking testosterone for symptoms he attributed to low testosterone after viewing Defendant's advertisements as prescribed.

49. Upon information and belief, on or about, Plaintiff commenced treatment with Testim after being prescribed this medication by his doctor.

50. Upon information and belief, plaintiff continued treatment with Testim, as prescribed by his doctor.

51. Upon information and belief, Plaintiff was diagnosed with injuries related to testosterone use. As a result, he was hospitalized, had to miss work, and for the rest of his life, he must take medication. Due to his injuries, he is now at markedly increased risk of additional cardiovascular disease, cerebrovascular accidents, and death.

52. Had Defendants properly disclosed the risks associated with testosterone, Plaintiff would have avoided the risk of stroke by either not using testosterone at all, severely limiting the dosage and length of use, and/or by closely monitoring the degree to which the drugs were adversely affecting his health.

53. The applicable statute of limitations period is tolled based on Defendants' fraudulent concealment of the dangers and adverse side effects of Testosterone from Plaintiff as more fully stated herein. Additionally, for the same reasons stated herein, Defendants are equitably stopped from raising the statute of limitations of defense.

54. Plaintiff did not suspect, nor did he have reason to suspect, that wrongdoing had caused his injuries, nor did Plaintiff have reason to suspect the tortious nature of the conduct causing the injuries, until recently and has filed the herein action well within the applicable statute of limitations period. Plaintiff had no knowledge of the defects in the Testim and the wrongful conduct of the Defendant as set forth herein, nor did Plaintiff have access to the information regarding other injuries and complaints in the possession of Defendant. Additionally, Plaintiff was prevented from discovering this information sooner because Defendant herein misrepresented and continue to misrepresent to the public, to the medical profession and to Plaintiff that the Testim is safe and free from serious defects and side effects and Defendant has fraudulently concealed facts and information that could have led Plaintiff to an earlier discovery of potential causes of action.

55. As alleged herein, as a direct, proximate, and legal result of Defendants' negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the drug testosterone, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to heart attack. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

FIRST CAUSE OF ACTION
STRICT LIABILITY – FAILURE TO WARN

56. Plaintiff incorporates by reference herein each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

57. Defendant is liable under the theory of product liability as set forth in §§ 402A and 402B of the Restatement of Torts 2d.

58. The Testim manufactured and/or supplied by Defendants was defective due to inadequate warnings or instructions because Defendants knew or should have known that the product created significant risks of serious bodily harm to consumers, and they failed to adequately warn consumers and/or their health care providers of such risks. The Testim manufactured and/or supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of Testim, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury.

59. As a direct and proximate result of Plaintiff's reasonably anticipated use of Testim as manufactured, designed, sold, supplied, marketed and/or introduced into the stream of

commerce by Defendants, Plaintiff suffered serious injury, harm, damages, economic and non-economic loss and will continue to suffer such harm, damages and losses in the future.

SECOND CAUSE OF ACTION
NEGLIGENCE

60. Plaintiff incorporates by reference herein each of the allegations set forth in this Complaint as though set forth herein.

61. At all times herein mentioned, Defendants had a duty to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, distribute, prepare for use, sell, prescribe and adequately warn of the risks and dangers of Testim.

62. At all times herein mentioned, Defendants negligently and carelessly manufactured, designed, formulated, distributed, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold Testim and failed to adequately test and warn of the risks and dangers of Testim.

63. Despite the fact that Defendants knew or should have known that Testim caused unreasonable, dangerous side effects, Defendants continued to market Testim to consumers including Plaintiff, when there were safer alternative methods of treating loss of energy, libido erectile dysfunction, depression, loss of muscle mass and other conditions Testim's advertising claims are caused by low testosterone.

64. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

65. Defendants' negligence was a proximate cause of Plaintiff's injuries, harm and economic loss which Plaintiff suffered, and will continue to suffer, as described and prayed for herein.

THIRD CAUSE OF ACTION
FOR BREACH OF IMPLIED WARRANTY

66. Plaintiff incorporates by reference here each of the allegations heretofore set forth in this Complaint as though fully set forth herein.

67. Prior to the time that the aforementioned products were used by Plaintiff, Defendants impliedly warranted to Plaintiff and Plaintiff's agents and physicians that Testim was of merchantable quality and safe and fit for the use for which it was intended.

68. Plaintiff was and is unskilled in the research, design and manufacture of the products and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using Testim.

69. Testim was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that Testim has dangerous propensities when used as intended and will cause severe injuries to users.

70. As a result of the abovementioned breach of implied warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

FOURTH CAUSE OF ACTION
FOR BREACH OF EXPRESS WARRANTY

71. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though fully set forth here.

72. At all times mentioned, Defendants expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants or their

authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Testim is safe, effective, fit and proper for its intended use. Plaintiff purchased Testim relying upon these warranties.

73. In utilizing Testim, Plaintiff relied on the skill, judgment, representations, and foregoing express warranties of Defendants. These warranties and representations were false in that Testim is unsafe and unfit for its intended uses.

74. As a result of the abovementioned breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

FIFTH CAUSE OF ACTION
FRAUD

75. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though set forth fully herein.

76. Defendants, from the time they first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed Testim, and up to the present, willfully deceived Plaintiff by concealing from them, Plaintiff's physicians and the general public, the true facts concerning Testim, which the Defendants had a duty to disclose.

77. At all times herein mentioned, Defendants conducted a sales and marketing campaign to promote the sale of Testim and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the benefits, health risks and consequences of using Testim. Defendants knew of the foregoing, that Testim is not safe, fit and effective for human consumption, that using Testim is hazardous to health, and that Testim has a serious propensity to cause serious injuries to its users, including but not limited to the injuries Plaintiff suffered.

78. Defendants concealed and suppressed the true facts concerning Testim with the intent to defraud Plaintiff, in that Defendants knew that Plaintiff physicians would not prescribe Testim, and Plaintiff would not have used Testim, if they were aware of the true facts concerning its dangers.

79. As a result of Defendants' fraudulent and deceitful conduct, Plaintiff suffered injuries and damages as alleged herein.

SIXTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

80. Plaintiff incorporates by reference herein each of the allegations set forth in this Complaint as though fully set forth herein.

81. From the time Testim was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiff's physicians and the general public, including but not limited to the misrepresentation that Testim was safe, fit and effective for human consumption. At all times mentioned, Defendants conducted a sales and marketing campaign to promote the sale of Testim and willfully deceive Plaintiff, Plaintiff's physicians and the general public as to the health risks and consequences of the use of the abovementioned product.

82. The Defendants made the foregoing representation without any reasonable ground for believing them to be true. These representations were made directly by Defendants, by sales representatives and other authorized agents of Defendants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

83. The representations by the Defendants were in fact false, in that Testim is not safe, fit and effective for human consumption, using Testim is hazardous to health, and Testim has a

serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by Plaintiff.

84. The foregoing representations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase and use of Testim.

85. In reliance of the misrepresentations by the Defendants, and each of them, Plaintiff was induced to purchase and use Testim. If Plaintiff had known of the true facts and the facts concealed by the Defendants, Plaintiff would not have used Testim. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

86. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiff suffered injuries and damages as alleged herein.

PUNITIVE DAMAGES ALLEGATIONS

87. Plaintiff incorporates by reference here each of the allegations set forth in this Complaint as though fully set forth herein.

88. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights of Plaintiff and other Testim users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Testim. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

89. Prior to the manufacturing, sale, and distribution of Testim, Defendants knew that said medication was in a defective condition as previously described herein and knew that those who were prescribed the medication would experience and did experience severe physical, mental,

and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said drugs to risk of injury or death from using Testim.

90. Despite its knowledge, Defendants, acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Testim and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in Testim. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Testim knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

91. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against Defendants as follows:

- (a) For general damages in a sum in excess of the jurisdictional minimum of this Court;
- (b) For medical, incidental, and hospital expenses according to proof;
- (c) For pre-judgment and post-judgment interest as provided by law;
- (d) For full refund of all purchase costs Plaintiff paid for testosterone;
- (e) For compensatory damages in excess of the jurisdictional minimum of this Court;

(f) For consequential damages in excess of the jurisdictional minimum of this Court;

(g) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;

(h) For attorneys' fees, expenses, and costs of this action; and

(i) For such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: December 5, 2014

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